Remarks

Prior to this amendment, claims 1-35 were pending in this application. Claim 13 is amended herein. After entry of this amendment, claims 1-35 are pending in this application.

Support for the amendment of claim 13 can be found in the specification at least at page 2, lines 27-32 and page 37, lines 24-28. No new matter has been added by these amendments.

Restriction Requirement

Claims 1-35 of this §371 National Stage application were indicated as being subject to a restriction requirement (finding of lack of unity). In particular, the following Groups have been designated:

Group I. Claims 1-12 and 19-35 drawn to a method of producing a protein with an increased activity or stability, a composition comprising a polypeptide, a method of increasing the activity or stability of a defensin polypeptide, and a method of increasing an immune response by administering a defensin polypeptide; and

Group II. Claims 13-18 drawn to a method of determining if a protein can be stabilized.

The Office action states that the inventions of Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Both of the Groups do in fact relate to a single special technical feature, which feature makes a contribution over the prior art. As such, all of the claims should be examined together. Applicants respectfully request that the requirement be withdrawn in light of the arguments and amendments herein.

Standard for Analyzing Unity of Invention

37 CFR § 1.475 requires unity of invention in a National Stage application such as this; unity of invention is present when a group of inventions are "so linked as to form a single general inventive concept." [*See* 37 CFR § 1.475(a).] "A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among

the inventions that involves at least one common or corresponding special technical feature." [MPEP § 1893.03(d). *See also* 37 CFR § 1.475(a).]

Further, "The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." [*See* 37 CFR § 1.475(a), emphasis added.]

These authorities make it clear that an analysis with regard to unity of invention occurs in two stages. First, is there a special technical feature shared among the claims/groups of inventions, such that they are **linked to form a single inventive concept**? If there is, then one asks whether that special technical feature **defines a contribution over the prior art** for each of the claimed inventions. If no relevant prior art is identified, then there can be no finding of lack of unity.

Applying the Standard in the Current Case

The Office action states that the special technical feature of Group I is a method of producing a protein by replacing an arginine residue with a tryptophan or phenylalanine residue and that the special technical feature of Group II is the method of determining if a protein can be stabilized. However, Applicants submit that the special technical feature of the invention as currently claimed is, in fact, the *replacement of an arginine residue capable of being ADP-ribosylated with a tryptophan residue or a phenylalanine residue in order to increase the activity or stability of a protein*. Applicants have amended claim 13 to clarify the linking inventive concept in Group II and submit that Groups I and II are indeed linked to form a single general inventive concept.

The recited special technical feature does define a contribution over the prior art for both Groups of inventions. For example, there is no reference of record in this case that discloses the replacement of an arginine residue capable of being ADP-ribosylated with a tryptophan residue or a phenylalanine residue in order to increase the activity or stability of a protein; the International Preliminary Examination Report (IPER) dated September 29, 2004, failed to identify a prior art reference of particular relevance and it specifically states that claims 1-35

"meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the presently claimed invention" (IPER, Section V). Moreover, the IPER did not state that there was a lack of unity of invention among the claims. In addition, no reference has been cited in the current Restriction Requirement, which would appear to be a clear admission that there is no relevant prior art. Thus, this special technical feature does define a contribution over the prior art for both Groups of inventions. This feature is a basis for patentability of Applicants' invention.

As required by 37 CFR § 1.475, the claims of Groups I and II have unity of invention because they are directed "to a group of inventions so linked as to form a single general inventive concept" because "there is a technical relationship among [the] inventions involving one . . . corresponding technical feature[]" – replacement of an arginine residue capable of being ADP-ribosylated with a tryptophan residue or a phenylalanine residue in order to increase the activity or stability of a protein – and this special technical feature "define[s] a contribution . . . over the prior art." As unity of invention exists between Groups I and II in the present application, Applicants request that the requirement be withdrawn, that Groups I and II be rejoined, and that the corresponding claims be examined in the current case.

Requirement of a Species Election

The Office action alleges that Groups I and II contain claims directed to more than one species of the generic invention and that these species "are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1" (Office action at page 2). Applicants traverse this species election.

As discussed above, Applicants submit that the claims are linked by a single general inventive concept. The claims reciting the alleged species (T cell chemotaxis, neutrophil recruitment, or cytokine release) each depend from a claim having the special technical feature. As the dependent claims contain all of the limitations of the claims from which they depend, the dependent claims also possess the same special technical feature. Since no prior art has been cited against the base claims, they (and the dependent species claims) are allowable. Moreover, the measurement of T cell chemotaxis, neutrophil recruitment, or cytokine release are all known

assays in the art for determining immunologic or T-cell activity. Thus, Applicants submit that the requirement of a species election in this case is inappropriate.

Election

Under protest, and only to comply with 37 CFR §1.499, Applicants hereby provisionally elect Examiner's Group I (claims 1-12 and 19-35). In addition, Applicants further elect T cell chemotaxis, with traverse. Applicants take the opportunity to remind the examiner that, as set forth in M.P.E.P. §809.02(a), "[u]pon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all of the limitations of an allowed generic claims as provided by 37 CFR 1.141."

In accord with 37 CFR §1.143, Applicant specifically reserves the right to petition to have the appropriateness of the finding of lack of unity/restriction requirement reconsidered, if it is maintained in spite of this response.

Conclusion

It is believed that the application is in condition for substantive examination. If any minor matters remain to be addressed prior to examination, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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